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10/696,381

10/28/2003

Albert K. Chin

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EXAMINER

SMITH, PHILIP ROBERT

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/696,381 | Applicant(s) CHIN, ALBERT K. | |
| | Examiner PHILIP R. SMITH | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

- [01] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/2008 has been entered.

Claim Rejections - 35 USC § 102

- [02] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [03] The rejection of claims 1-2,6,10 as being anticipated by as being anticipated by Horzewski (5,318,588) set forth in the Office action of 12/26/2007 are withdrawn in view of the amendments of 4/7/2008.

Claim Rejections - 35 USC § 103

- [04] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [05] Claims 1, 4-8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Gibson (702,789).
- [06] With regard to claim 1:
- [06a] Horzewski discloses an apparatus for performing a surgical procedure comprising:
- an inner cannula ("dilator 150" 12/49) having an elongated body and a tip ("bulbous region 127" 12/64) that is positioned at a distal end of the elongated body and that is

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configured to dissect tissue ("dilator 150 contains a guidewire channel 122" 12/49);
and

- an outer expandable sheath ("side arm sheath 90" 11/67) disposed about the inner cannula and configured to expand in an outward direction ("accommodate positive radial expansion over a specific range of radial dimensions" 12/7-9) responsive to the tip of the inner cannula slidably passing longitudinally through the sheath ("Withdrawal of the dilator [150], however, through the confines of the sheath, increases the profile of the delivery channel to the desired profile as bulbous region 127 is withdrawn through the shaft" 13/12-15).

[06b] Horzewski does not disclose:

- That the outer expandable sheath comprises first and second shells.

[06c] Gibson discloses:

- an outer expandable sheath ("tube A" 1/28) configured to expand in an outward direction responsive to the tip of an element ("rod D" having "plunger D2" 2/65) slidably passing longitudinally through the sheath (2/71-89). Gibson further discloses that the outer expandable sheath comprises a first shell and a second shell ("segmental bars e'," 2/60-70) adjacently aligned along longitudinal edges thereof.

[06d] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the outer expandable sheath having resiliently connected first and second shells disclosed by Gibson be substituted for the outer expandable sheath disclosed by Horzewski. It is obvious to substitute one known element for another to obtain predictable results. Radially expansive tubes are known in the art, as are radially expansive shells. A

skilled artisan could have substituted one for the other, and the resulting substitution would have been predictable.

- [07] With regard to claim 4: Gibson further discloses and a resilient connector ("thin soft rubber sheath C," 2/81) attached between the first and second shells for resiliently urging the longitudinal edges of the shells together.
- [08] With regard to claim 5: Gibson further discloses that the outer expandable sheath further comprises a retainer ("nut E," 2/74) disposed near the proximal end of the shells for retaining the shells against relative longitudinal movement during passage of the inner cannula through the outer expandable sheath.
- [09] With regard to claim 6: the inner cannula and outer expandable sheath disclosed by Horzewski in view of Gibson are separable to allow the outer expandable sheath to remain in place at a surgical site as the inner cannula and the tip attached thereto are withdrawn ("installing dilators of progressively larger cross-sectional profiles" 13/20-22).
- [10] With regard to claim 7: the resilient connector disclosed by Gibson resiliently urges a distal end of the first shell toward a distal end of the second shell (a point indicated by "a2" in the figures) to form an inner dimension at the distal end of the outer expandable sheath smaller than the outer dimension of the tip in the absence of an outwardly expansive force applied to the distal end of the outer expandable sheath in response to the tip passing through the distal ends of the shells.
- [11] With regard to claim 8: Gibson further discloses that the outer expandable sheath further comprises: a second resilient connector ("nut E," 2/74) disposed to resiliently urge a proximal end of the first shell toward a proximal end of the second shell to form an inner dimension at the proximal end of the outer expandable sheath smaller than the outer dimension of the tip in the absence of an

outwardly expansive force applied to the proximal end of the outer expandable sheath in response to the tip passing through the proximal ends of the shells.

- [12] With regard to claim 10: Horzewski further discloses that the tip is disposed on the inner cannula distally of the outer sheath (since the inner cannula and the outer sheath disclosed by Horzewski are inherently separable, the tip "127" of Horzewski is inherently capable of being located anywhere, including "distally of the outer sheath". However, Horzewski explicitly shows in Figure 5A that this is the intended use of the inner cannula and outer sheath), the tip ("127") further comprising a distal tapered end ("leading taper 123") for dissecting tissue, a proximal tapered end ("expansion taper 124"), and an enlarged intermediate portion having an outer dimension greater than an inner dimension of the sheath for exerting lateral expansion force against the outer expandable sheath responsive to slidable passage of the tip longitudinally through the outer expandable sheath ("maximal profile of the bulbous region 127 of dilator 150 corresponds to the intended channel profile of the device" 13/14, as noted above).

Additional Claim Rejections - 35 USC § 103

- [13] Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Gibson (702,789) and in further view of Vandegrift (2,201,749).
- [14] As noted above, Horzewski in view of Gibson discloses first and second shells adjacently aligned along the longitudinal edges thereof.
- [15] Horzewski in view of Gibson does not disclose that the first and second shells are configured as substantially half cylindrical segments. Instead, Gibson discloses "segmental bars" which are adjacently aligned along the longitudinal edges thereof. Figure 3 shows five such "segmental bars".

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- [16] Vandegrift discloses an expanding vein tube which is "split vertically throughout the greater portion of its length along diametrically opposed lines as at 2,2 which provide semi-circular legs 3 and 4" (1/51-54). The tube disclosed by Vandegrift accomplishes a similar function to that of Horzewski in view of Gibson: expansion of an outer shell in response to a "plunger" or "dilator" being passed through it.
- [17] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that an outer shell having two half cylindrical segments configured to expand in response to a dilator ("3 and 4" as disclosed by Vandegrift) be substituted for the outer shell having five "segmental bars" which are configured to expand in response to a dilator (as disclosed by Horzewski in view of Gibson). A skilled artisan would be motivated to do so in order to provide for simpler manufacturing of the device, and fewer longitudinal slits with which to potentially injure the patient.

Response to Arguments

- [18] Applicant's arguments filed 4/7/2008 have been fully considered but they are not persuasive.
- [19] Applicant contends that "neither Horzewski et al. '588 nor Gibson '789 disclose or even hint at expanding an outer sheath with a tip that is positionable forward or distally of the outer sheath and that expands the outer sheath in passing through it." On the contrary, Horzewski discloses precisely an outer sheath with a tip that is positionable forward or distally of the outer sheath and that expands the outer sheath in passing through it, as noted above. Gibson teaches an analogous expandable sheath that may be composed of adjacent shells.

Conclusion

- [20] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.
- [21] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [22] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Philip R Smith/

Examiner, Art Unit 3739

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739